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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,569	02/21/2002	Gholam-Reza Zadno-Azizi	17075-003004 / 0102D	4156

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/081,569	ZADNO-AZIZI ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2007 has been entered.

Declaration

Upon further review of the 1.132 declaration filed on October 20, 2003, the declaration has been found non-persuasive for the below reasons. Although it may be true that the definition of "fluid" may include liquids and gases and further the definition of pulmonic or pulmonary may relate the lungs or heart, it is the examiners opinion that the applicant does not have support in the description for the more narrow species or subgenus (air, lung and bronchial passageway; see below).

Specification

The amendment filed April 25, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Each new paragraph recited in the April 25, 2006 amendment. Specifically every reference to "lung", "air", and "bronchial".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not have support for the subject matter pertaining to all recitations of "bronchial passageway", "air flow", and "lung".

The applicant has argued in their previous 1.132 declaration and corresponding arguments that since the specification discloses the term "pulmonic", applicant inherently has support for placement within a lung, specifically into a bronchial passageway. Further that since the specification discloses the term "fluid", applicant inherently has support for air flow. The examiner disagrees. First lets look at the definition of the terms found in Stedman's Medical Dictionary, 27th Edition, Lippincott Williams, and Wilkins, 2000:

Pulmonary: "Relating to the lungs, to the pulmonary artery, or to the aperture leading from the right ventricle into the pulmonary artery." Syn. Pulmonic.

As can be seen from the above recitation, pulmonary refers to a multitude of bodily parts, thus having multiple definitions. Lets look at these separately. The pulmonary artery is part of the *vascular system* and carries *blood* (not air, and further not located in a bronchial passageway). The aperture is the location of the pulmonary or pulmonic valve located in the *heart* for the pumping of *blood* (also not air, and further not located in a bronchial passageway). The other

definition "relating to the lungs" does refer to lungs, however it is unclear from the definition whether it encompasses airflow in the lungs, blood flow to and in the lungs, both, or neither. Although bronchial passageways are located in the lungs, so are a multitude of other bodily parts (pulmonary arteriole, pulmonary venule, alveolar sac, lung epithelium, lung smooth muscle), and that does not mean that pulmonary provides coverage and support for all bodily parts located in the lung. Stedman's Medical Dictionary shows diagram of lung anatomy on pg.1035, a blow up of a lung wherein the pulmonary structures (arteriole and venule) run adjacent and are *separate structures* to the bronchiole. This would lead to the conclusion that bronchiole are not pulmonary, as they are shown to be different structures.

Further, even if bronchial passageways were considered to be pulmonary/pulmonic, it is not clear and concise from the original disclosure, that applicants had possession of such a narrower species or subgenus embodiment of lung, air flow through a bronchial passageway at the time the invention was made. See MPEP 2163.05, II. Narrowing or subgeneric claim. "The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph." See also In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972), "Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads."

The applicant's original disclosure refers to "pulmonic" in the generic sense and also in a more specific sense referring to only blood flow in the vascular system. See page 2 of the applicant's specification, under Background of the Invention: "The *pulmonic valve* associated

with the *heart* is yet another native flow control mechanism which can exhibit incompetence either congenitally, though disease or iatrogenically due to treatment of *pulmonary stenosis. A one-way valve positioned distal to the native pulmonic valve within the pulmonary artery could be of substantial benefit in overcoming this problem.*" Emphasis added. Applicant is here describing the problem to be located at the pulmonary artery in the blood stream. Applicant then goes on to describe their invention referring to their device throughout the remainder of the specification broadly as pulmonic or pulmonary valve/flow control device. The only species or subgenus disclosed or even envisioned is within the pulmonary artery, in the heart or in the vascular system. Applicant only has support for the broad genus of pulmonic valve/fluid control device, or the specific species or subgenus of placement in the pulmonary artery. Nowhere in the original disclosure is there any reference to the lungs or placement within a bronchial passageway, the applicant does not have support for such an embodiment. Because lung and bronchial placement is not supported, neither is airflow. Although applicant has support for fluid flow, the only application disclosed or referred to is related to urinary flow or blood flow and thus air flow (a more narrow specific species) is not supported, envisioned and is also considered new matter. One skilled in the art upon reading the applicant's original disclosure would not conclude or assume pulmonary or pulmonic to mean bronchial air passageways in the lung. The applicant's invention is directed to a valve that opens and closes for one-way fluid flow in the vascular system, where native valves are present. The invention is directed to replacing the native valves or their function in the heart or venous system (or uninary tract in a different disclosed embodiment). No native valves are known to the examiner to be located in the bronchial passageways for regulating the flow of air throughout the lungs. Since the present

invention is related to valves and replacement of native valves function (specifically referring to the vascular system), it is not apparent that the invention would be direction to bronchial air passageways in the lung, since such a location does not have valve and would not seem to have a need for valves. It is also important to note that even in applicant's submitted 1.131 declaration on October 20, 2003, Exibit 1, applicant has provided evidence of maximum tolerated pressures the valve may withstand under the influence of urine or blood for urinary incontinence or venous vascular applications. Again even here, no support is found for pressure for the application of air flow in the bronchial passageways.

The specification does not seem to provide adequate support for "lung", "air" and "bronchial". Further, the specification does not convey with reasonable clarity to those skilled in the art, that the applicant was in possession of the invention claimed (lung, air, and bronchial). *Vas-Cath* 935 F.2d at 1563-64, 19 USPQ2d at 1117. The original disclosure is not believed to show "in such full, clear, concise, and exact terms" possession of the application of lungs, air flow, or bronchial placement. 35 U.S.C. 112, para. 1. Cf. *Fields v. Conover*, 443 F.2d 1386, 1392, 170 USPQ 276, 280 (CCPA 1971).

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-27 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bessler et al. (US 5,855,601). Referring to claims 20, 23, 26, and 27, Bessler discloses a fluid flow device (20, 30; fig.1, 4) and system (including outer sheath 91) *capable of* placement into a bronchial passageway comprising a cylindrical resilient

seal of annular configuration (cuff 25 or 37), a one-way valve (24, 36; col.5, lines 37-39) movable between an open and closed configuration (col.3 line66-col.4 line 1), the device completely blocking flow when in the closed configuration (one-way flow; therefore inherently blocks reverse flow), a frame (21, 31) couple to the valve and having a passageway in communication with a passageway in the valve (when valve is open configuration, the passageways are coaxial and the same thus in communication with one another), the frame movable between an insertion state (seen in fig.5) and an anchoring state (seen in fig.4 with a larger transverse dimension), the frame being self-expandable (col.3, lines 47-55), and a valve support (considered to be bottom or proximal portion of cuff 25, 37 OR 27 seen in fig.1, more clearly shown at bottom of stent in fig.5) that connects the seal (upper cuff 25, 37) to the valve (24, 36), the valve support moveable with the frame (see fig.5, wherein portion 25, 37, and 27 all expand as the frame expand to a larger diameter). Bessler has shown the device at a relaxed state prior to implantation in figures 1-4. In each of these figures the valve is shown to be in the closed configuration. Bessler's valve is considered to be inherently biased in the closed configuration since it is shown closed in the relaxed state without forces acting upon it. It would have been obvious if not inherent from the figures and specification, to one having ordinary skill in the art at the time the invention was made, to bias the valve closed such that a stronger seal is made upon closure thus preventing any chance of retrograde flow.

Referring to claims 22 and 25, Bessler discloses the valve to have a slit through which fluid may flow (slits seen between leaflets in figs.2-4; col.3, lines 65-66).

Referring to claims 21 and 24, Bessler discloses a valve with an expanded outer diameter of 1.5-3.0 cm). Bessler's valve is capable of being inserted into a bronchial passageway which is

a little bit smaller in diameter (claimed 0.886cm or 0.349 inches). Because Bessler's valve is expandable, it will have diameters less than 1.5-3.0 cm. Bessler's device is capable of being placed in a bronchial passageway which has a claimed dimension of 0.886 cm, since Bessler's device is expandable, and will only partially expand in such a location and will inherently have the claimed diameter upon partial expansion when placed in such a location. If it is not inherent that Bessler's valve have such a diameter, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the diameter claimed (0.349in/0.886 cm), since when the general conditions of a claim (structural features of a valve for insertion into a bodily passageway) are disclosed in the prior art (Bessler), it is not inventive to discover the workable or optimum ranges (smaller diameters for different passageways in the body) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 20-27 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suh et al. (US 6,027,525). Referring to claims 20, 23, 26, and 27, Suh discloses a fluid flow device (fig.6) and system (including outer sheath, "stent insertion device", col.4, lines 21-23) *capable of* placement into a bronchial passageway (col.2, lines 2-6, 15-18; col.3, lines 1-2) comprising a cylindrical resilient seal of annular configuration (2, 3), a one-way valve (72, 74) movable between an open and closed configuration (col.6, lines 3-13), the device completely blocking flow when in the closed configuration (one-way flow; therefore inherently blocks reverse flow), a frame (1) couple to the valve (72, 74) and having a passageway in communication with a passageway in the valve (when valve is open configuration, the passageways are coaxial and the same thus in communication with one another), the frame movable between an insertion state and an anchoring state (col.4, lines 20-

23), the frame being self-expandable (col.3, lines 19-21), and a valve support (end portion of graft 2, 3 near connection to valve 72, 74) that connects the seal (2, 3) to the valve (72, 74), the valve support moveable with the frame (2, 3, located along the expandable frame and expands with the frame). Suh has shown the device at a relaxed state prior to implantation in figure 6. In each of these figures the valve is shown to be in the closed configuration. Suh's valve is considered to be inherently biased in the closed configuration since it is shown closed in the relaxed state without forces acting upon it. It would have been obvious if not inherent from the figures and specification, to one having ordinary skill in the art at the time the invention was made, to bias the valve closed such that a stronger seal is made upon closure thus preventing any chance of retrograde flow.

Referring to claims 22 and 25, Suh discloses the valve to have a slit (7', opens when in open configuration) through which fluid may flow.

Referring to claims 21 and 24, Suh discloses a valve with an expanded outer diameter of any dimension d for the claimed passageways (col.5, lines 1-47). Since Suh's valve is disclosed to be placed in lung passageways and is disclosed to have any diameter by the disclosed equation, Suh may inherently have a diameter of 0.349 inches. Especially since the valve of Suh is expandable, the valve has a multiplicity of diameters ranging from the fully compressed state to the fully expanded state. If it is not inherent that Suh's valve have such a diameter, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the diameter claimed (0.349in/0.886 cm), since when the general conditions of a claim (structural features of a valve for insertion into a bodily passageway) are disclosed in the prior art (Suh), it is not inventive to discover the workable or optimum ranges (smaller diameters for

different passageways in the body) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/

BRUCE SNOW
PRIMARY EXAMINER